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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,455

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Helmut Goldmann

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

10/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,455	Applicant(s) GOLDMANN, HELMUT	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/7/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Objections

Claim 36 is objected to because of the following informalities: it is unclear how the coatings of the vascular prosthesis are intended to be layered as the first coating of the polymer material seals off the textile's pores, and the second coating mentioned is described as leaving the pores open. Appropriate correction is required.

Claims 37-39 are objected to because of the following informalities: it is unclear which coating the claim is referring to. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 37, and 40-42 are rejected under 35 U.S.C. 103(a) as being anticipated by Trogolo et al. (U.S. Pat. No. 6,296,863) in view of Ragheb et al. (US Pat. No. 5,873,904). As best interpreted by the examiner, Trogolo et al. discloses the following of claim 36: an antibacterial vascular prosthesis, comprises a porous textile material comprising: a substantially non-absorbable or only slowly absorbable polymer material (10, 18; col. 3, lines 2-4, 15-21) coating and sealing a surface of the textile surface and pore surfaces of the textile material (col. 2, line 63 through col. 3, line 10); a coating comprising an absorbable material (col. 8, lines 31-40) and silver ions (20; col. 3, line 59 through col. 4, line 30); and wherein the substantially non-

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absorbable or only slowly absorbable polymer material further comprises silver atoms of the silver layer impressed into the polymer surface (col. 3, lines 59-65).

Trogolo et al. does not disclose using a closed, pure elemental silver to serve as a layer on the prosthesis. However, Ragheb et al. teaches an implantable medical device that has layers of pure elemental silver in col. 22, lines 36-50 and col. 26, line 65 through col. 27, line 4 for the purpose of utilizing the material's antibacterial properties. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Trogolo et al. to have a closed layer of pure elemental silver in order to utilize the material's antibacterial properties.

Regarding the ranges of thickness, it would have been obvious to one having ordinary skill in the art at the time the invention was made to create a silver layer with the claimed properties, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Trogolo et al. discloses the following of claim 37: the prosthesis as claimed in claim 36 wherein the coating comprises optionally crosslinked biological material (col. 8, lines 31-33).

Claims 40 and 41 are shown in Figures 3-4.

Trogolo et al. discloses the following of claim 42: the prosthesis as claimed in claim 36, wherein a sintered material is used with the textile material (col. 3, lines 2-4).

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Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Ragheb et al., further in view of Shikani et al. (U. S. Pat. No. 5,762,638).

Regarding claim 38, Trogolo et al., as modified by Ragheb et al., does not disclose using absorbable, synthetic polymers and copolymers on the coating. In the field of medical devices, Shikani et al. teaches in col. 14, lines 8-25, 37-47 that synthetic polymers and co-polymers make excellent coating materials on prosthetic devices because they are not prone to swelling and are non-bioerodible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to potentially replace Trogolo et al.'s collagen coating with a synthetic polymer as both are known in the art to have properties that are necessary for coatings on prosthetics.

Regarding claim 39, Trogolo et al., as modified by Ragheb et al., does not disclose using active substances in the absorbable coating. Shikani et al. teaches in col. 5, lines 47-62 that it is known in the art to place drugs in the outer coating of a device such that it can be programmed to be released after a certain period of time based on the choice of the outer coating. This will help prevent inflammation and granulation tissue at the sites where these prosthetics are implanted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use such an outer coating on Trogolo et al.'s prosthesis to prevent inflammation and granulation tissue at the site of implantation.

Response to Arguments

Applicant's arguments with respect to claims 36-42 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774